



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of )  
Joseph L WITZTUM ) FOR: REAGENTS FOR DIAGNOSING,  
Serial No.: 10/706,659 ) IMAGING AND TREATING  
Filed: November 12, 2003 ) ATHEROSCLEROTIC DISEASE  
Group  
Art Unit: unknown

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 and 1.98

Mail Stop DD  
Commissioner for Patents  
P.O. Box 1451  
Alexandria, VA 22313-1450

Attention: Examiner

Dear Sir:

Applicants submit herewith references of which they are aware, which they believe may be material to patentability of the invention disclosed and claimed in the above-cited application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450 Alexandria VA 22313-1450 on:

March 26, 2004  
(Mailing Date)

Cindy Guido

(Typed Name)

(Signature)

March 26, 2004  
(Date of Signature)

Applicants are submitting herewith copies of the references which are set forth on the attached Form PTO/SB/08A. As all relevant parts of the references are in the English language, no explanation of the references is provided herein.

This Information Disclosure Statement is submitted within three (3) months of the filing date of the above-cited application or of the date of entry into the national phase of the application or prior to the mailing date of a first Office Action thereon, whichever has occurred last, such that no fee is required.

Further, while the references provided in this Information Disclosure Statement may be material to patentability pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any reference referred to herein is prior art for this invention unless specifically designated as such.

Also, in accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists.

Respectfully submitted,

Dated: March 26, 2004

By:   
Colleen McKiernan  
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Registration No. 48,570

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Docket No.: 6627-P0045D



PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031  
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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	10/706/659
Filing Date	November 12, 2003
First Named Inventor	Joseph L. WITZTUM
Art Unit	unknown
Examiner Name	unknown
Attorney Docket Number	6627-P0045D

Total Number of Pages in This Submission

**ENCLOSURES (Check all that apply)**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance communication to Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below):<br>PTO/SB08A and PTO/SB08B (2)<br>16 Cited References<br>Return Postcard |
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Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Colleen McKiernan
Signature	
Date	March 26, 2004

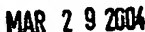
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*(Use as many sheets as necessary)*

Sheet	1	of	3
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Application Number	10/706,659
Filing Date	11/12/2003
First Named Inventor	WITZTUM et al
Art Unit	unknown
Examiner Name	unknown
Attorney Docket Number	6627-P0045D

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	1 <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	4	WO/98/21581	5-22-1998	Tsimikas et al	whole document	
	5	WO 94/23302	10-13-1994	Selley	whole document	

**Examiner  
Signature**

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO

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STATEMENT BY APPLICANT**

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Application Number	10/706,659
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Art Unit	unknown
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Sheet 2 of 3

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	6	Hoorko S. Miller, E. Dudl E. et al Antiphospholipid antibodies are directed against epitopes of oxidized phospholipids: recognition of cardiolipin by monoclonal antibodies to epitopes of oxidized LDL. J. Clin. Invest.; 1996;98: 815-825	
	7	Huse WD, Sastry L, Iverson SA, Klang AS, Alting-Mees M, Burton DR, Benkovic SJ, Lerner RA. Generation of a large combinatorial library of immunoglobulin repertoire in phage lambda. Science . 1989;246:1275-1281	
	8	Palinski W, Horkko, S. Miller et al. Cloning of monoclonal autoantibodies to epitopes of oxidized lipoproteins for apo E-deficient mice. Demonstration of epitopes of oxidized LDL in human plasma. J. Clin. Invest 1996;98:800-814	
	9	Shaw P.X, Horkko, S. Chang, M-K Curtiss, L.K. Palinski, W. Silverman, G.J. and Witztum, J.L. Natural antibodies with T15 Idiotypic may act in atherosclerosis, apoptotic clearance and protective immunity. J. Clin. Invest. 105:1731-40, 2000	
	10	Wu CC, Chang SW, Chen MS, Lee YT. Early change of vascular permeability in hypercholesterolemic rabbits. Arterioscler Thromb Vasc Biol. 1995, 15-529-533	
	11	Libby P. et al. Stabilizing of atherosclerotic plaques: New mechanisms and clinical targets. Nature Medicine. Vol 8, No. 11, 1257-1262-Nov. 2002	
	12	Narula, J. et al. Strategic targeting of atherosclerotic lesions. Journal of Nuclear Cardiology, Part 1, pp. 81-90 Jan./Feb 1999	
	13	Strauss, H.W. Imaging of atherosclerosis-A worthy challenge. Journal of Nuclear Cardiology, Vol 3, No 3, pp.278-280 May/June 1996	
	14	Tsimikas, S. et al. In vivo uptake of Radiolabeled MDA2, an oxidation-specific monoclonal antibody provides an accurate measure. Arterioscler Thromb, Vasc. Biol., Vol 20:689-697.2006	
	15	Holovet, P. et al, Monodialdehyde-modified low density lipoproteins in patients with atherosclerotic disease. J. Clin Invest. Vol 95:2611-9. 1995	

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	16	Tsimikas S. Palinski W, Halpern SE, Yeung DW, Curtiss LK, Witztum JL. Radiolabeled MDA2, an oxidation-specific Mab, identifies native atherosclerotic lesions in vivo. J. Nucl Cardiol. 1999; 6:41-53	

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